



DEPARTMENT OF HEALTH AND HUMAN SERVICES

m43c17
Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

August 24, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA-00-93

Dr. Kuo Ching Yee, President
Ameritek, Inc.
7030 35th Avenue NE
Seattle, Washington 98115

WARNING LETTER

Dear Dr. Yee:

During an inspection of your firm located in Seattle, Washington, conducted from April 3 through April 13, 2000, an investigator from the Food and Drug Administration (FDA) determined your firm manufactures, packages, labels and distributes the dBEST One-Step HIV1/HIV2 test kit. The test kit is a device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection determined the dBEST One Step HIV1/HIV2 test kit is in domestic commerce because the test kits are sold by your firm to distributors in the United States. Therefore, the dBEST One Step HIV1/HIV2 test kit is adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f) of the Act and there is no approved application for premarket approval in effect pursuant to section 515(a), or an approved application for investigational device exemption under section 520(g). Additionally, your dBEST One Step HIV1/HIV2 test kit is misbranded under section 502(o) of the Act, because you did not submit information that shows your devices are substantially equivalent to other devices that are legally marketed.

The dBEST One-Step HIV1/HIV2 test kit is also adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the current Good Manufacturing Practices (CGMP) for medical devices, as set forth in the Quality Systems Regulations, Title 21, Code of Federal Regulations (21 CFR), Part 820 as follows:

- The inspection discloses that the devices have been exported in violation of Section 801(e)(2) of the Act since you did not receive permission from the FDA to export the devices or failed to comply with the export requirements of Section 802 of the Act. Specifically, you have not

demonstrated that the export of the devices was in compliance with the requirements outlined in Section 802(b)(1)(A) of the Act.

- The dBEST One-Step HIV-1/HIV-2 test kit, which is exported, is in violation of section 802(f)(1) of the Act, because it is adulterated within the meaning of section 501(h) of the Act as described above.
- You are in violation of Section 802(g) of the Act since you failed to comply with the requirements outlined in the Act, in that a simple notification was not provided to the Secretary identifying the devices and the country to which such devices were being exported when the exporter first began to export the devices to a country not listed in Section 802(b)(1)(A)(i) or (ii) of the Act. For example you ship to several unlisted countries such as Nigeria, Thailand, Pakistan and Korea.
- Failure to establish and maintain procedures for identifying product during all stages of receipt, production, distribution and installation to prevent errors in that there is no documentation to demonstrate which individual production sheets are covered by a specific Certificate of Analysis [21 CFR 820.60].
- Failure to establish, maintain and document procedures to control product that does not conform to specified requirements in that you have not documented the disposition of nonconforming product, and defined the responsibility for review and the authority for the disposition of nonconforming products. [21 CFR 820.90(a) and (b)].
- Failure to establish complaint handling procedures [21 CFR 820.198].

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and all other applicable regulations. The specific violations noted in this letter and in the form FDA 483 issued to you at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violation identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Other Federal Agencies are advised of the issuance of all Warning Letters regarding medical devices so they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without

Dr. Kuo Ching Yee, President
Ameritek, Inc., Seattle Washington
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further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. Include an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Direct your reply to Bruce W. Williamson, Compliance Officer, at the above address. If you have any questions concerning this matter you may address them to Mr. Williamson at (425) 483-4976.

Sincerely,

A handwritten signature in dark ink, appearing to read "Charles M. Breen", with a long horizontal flourish extending to the right.

Charles M. Breen
District Director